

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

TEXAS MEDICAL ASSOCIATION, *et al.*,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES, *et al.*,

Defendants.

Civil Action No. 6:21-cv-00425-JDK

**DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT
AND MEMORANDUM IN OPPOSITION
TO PLAINTIFFS' SUMMARY JUDGMENT MOTION**

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For the reasons stated below, the Defendants respectfully request that the Court award summary judgment in their favor.

INTRODUCTION

Millions of Americans, at one time or another, may face a critical decision whether to seek health care services “in network” or “out of network”—that is, from a provider that is under contract with the patient’s health insurance plan, or from a provider that is not. As anyone familiar with health insurance can attest, the cost difference between receiving care from an in-network versus an out-of-network provider can be substantial. And, in many cases, a patient might not be able to avoid these costs by choosing an in-network provider.

For example, in an emergency, the patient might be given care by a provider that turns out not to be in their network. Or the patient might carefully schedule a procedure at an in-network facility but, unbeknownst to him or her, a portion of the service could be performed by an out-of-network provider. Cases like these have often led to staggering, and sometimes ruinous, medical bills. What is more, this phenomenon of surprise billing has also inflated the cost of in-network care, because many providers have simply refused to negotiate for fair in-network payment rates, with the awareness that they could fall back on the option of demanding much higher out-of-network payments.

In late December 2020, Congress enacted the No Surprises Act (“NSA,” or “the Act”). The principal aim of the NSA is to address this “surprise billing” problem. The NSA limits a patient’s share of the cost of emergency services delivered by out-of-network providers, or of the cost of non-emergency services provided by certain out-of-network providers in in-network facilities absent patient consent. The Act also addresses how a payment dispute in these situations between an out-of-network provider and a group health plan or health insurance issuer will be resolved. The Act creates an arbitration mechanism whereby each party will submit its proposed payment amount and an independent, private arbitrator, known as a “certified IDR entity,” will select between the two offers. Congress also directed the Departments that are the Defendants in this suit to create rules to establish this arbitration process, and to do so within one year of the NSA’s enactment.

The principal provisions of the Act went into effect on January 1 of this year, and the first

arbitrations of payment disputes will likely begin in April. But providers and insurers needed to prepare in advance for their new obligations and responsibilities under the Act. To accommodate this need, the Defendants—the Department of Health and Human Services (HHS), the Department of Labor, and the Department of the Treasury (the Departments), along with the Office of Personnel Management (OPM)—published two interim final rules, one in July 2021, and a second one in September 2021.

The Plaintiffs here take issue with portions of the second rule. Specifically, they object to that rule’s instructions that the arbitrator, when choosing between the competing amounts proposed by the insurer and the provider, should look first to a figure known in the Act as the “qualifying payment amount,” or QPA. This amount is based on the calculation of the median contracted rate for a given medical service—that is, what an insurer typically would have paid for the service, if it had been performed by an in-network provider. The Plaintiffs contend that the Departments, in issuing these instructions, unlawfully departed from the text of the Act, which on their reading leaves it to the arbitrators’ virtually unfettered discretion to rely on any information he or she may wish to consider in choosing one of the parties’ competing offers.

The Plaintiffs’ challenge fails, for multiple reasons. First, they lack standing. The Plaintiffs have not presented concrete evidence that they will be harmed by the rule. An arbitrator with unconstrained discretion could just as easily pick a lower payment amount, after all. Article III places the burden on the Plaintiffs to prove that the rule causes them a concrete injury, and they have failed to meet that burden. Second, the rule comports with the statutory text. The rule, like the statute, sets forth a series of factors for the arbitrator to consider; the arbitrator begins with the qualifying payment amount, and then proceeds to consider what the statute describes as “additional” circumstances. The rule leaves ample room for the arbitrator to incorporate these additional circumstances into his or her decision, in accordance with the statute. And *Chevron* deference is owed to the rule, which was promulgated in response to a Congressional assignment of authority to the Departments to establish the Act’s arbitration process. Third, the Departments properly established the arbitration process through an interim final rule, both because the relevant statute expressly granted them interim

rulemaking authority, and because regulated entities' need for advance guidance gave the Departments good cause to proceed on an interim basis.

For all these reasons, the Defendants' motion for summary judgment should be granted, and the Plaintiffs' motion for summary judgment should be denied.

STATEMENT OF THE ISSUES

1. Have the Plaintiffs met their burden under Article III to prove they have standing to challenge the arbitration rule, where they have provided no concrete evidence that they will suffer any injury from the operation of that rule?

2. Did the Departments reasonably exercise the rulemaking authority that Congress granted them in the No Surprises Act by establishing a process whereby an arbitrator, in setting a payment amount for an out-of-network medical service, will first consider the qualifying payment amount before considering the "additional circumstances" described in the Act?

3. Did the Departments properly exercise the authority that Congress has granted to them to issue interim final rules as they find to be appropriate, where the failure to issue an interim final rule would have resulted in delays in the operation of key provisions of the No Surprises Act?

STATEMENT OF UNDISPUTED MATERIAL FACTS

I. Providers' Surprise Billing Practices Have Imposed Devastating Financial Consequences on Patients and Have Driven Up the Overall Cost of Health Care.

Congress enacted the No Surprises Act to address a "market failure" that gave certain health care providers little incentive to negotiate fair prices in advance for their services, resulting in exorbitant bills to patients and "highly inflated payment rates" for those services. H.R. REP. NO. 116-615, pt. I, at 53 (Dec. 2, 2020).

Most health plans and health insurance issuers "have a network of providers and health care facilities (participating providers or preferred providers) who agree by contract to accept a specific amount for their services." *Requirements Related to Surprise Billing: Part I*, 86 Fed. Reg. 36,872, 36,874 (July 13, 2021). "By contrast, providers and facilities that are not part of a plan or issuer's network (nonparticipating providers) usually charge higher amounts" than the in-network rates negotiated

between insurers and providers. *Id.* When an individual receives care out of network, the insurer could decline to pay for the services, or could pay an amount lower than the provider's billed charges, leaving the patient responsible for the remainder of the bill. *Id.*

"A balance bill may come as a surprise for the individual." *Id.* Surprise billing occurs, for example, when a patient receives care from a provider whom the patient could not have chosen in advance, or whom the patient did not have reason to believe would be outside the network of the patient's insurance plan. *Id.* These bills have arisen most frequently in two circumstances. First, in emergency situations, a patient may be unable to choose which emergency department he or she goes to (or is taken to); even if the patient goes to an emergency department that is in-network, he or she may still receive care from nonparticipating providers working at that facility. *Id.* Second, a patient may schedule a medical procedure in advance at an in-network hospital or facility, but may not be aware that providers of ancillary services, such as radiologists, anesthesiologists, or pathologists, are out-of-network. *Id.* "Unlike most medical services, for which patients have an opportunity to seek in-network providers, patients generally are not able to choose these emergency and ancillary providers." Erin L. Duffy et al., *Policies to Address Surprise Billing Can Affect Health Insurance Premiums*, 26 AM. J. MANAGED CARE 401, 401 (2020).

In either of these circumstances, the patient's inability to choose an in-network provider has created a distortion in the market wherein these providers have little incentive to negotiate fair prices in advance for their services, or to moderate their charges for out-of-network care. "Emergency physicians and anesthesiologists receive a flow of patients based on individuals electing care at the hospital in which they practice. And that volume will be the same regardless of whether the physician is in- or out-of-network. Because volume does not depend on prices set by providers in these no choice specialties, going out-of-network frees them to bill patients at essentially any rate they choose. And, as would be expected, we see that physician specialties that are able to bill out-of-network have extraordinarily high charges compared to other doctors." *Examining Surprise Billing: Protecting Patients from Financial Pain: Hearing Before the H. Comm. on Educ. and Labor, Subcomm. on Health, Employment, Labor and Pensions*, 116th Cong. 8 (2019) (statement of Christen Linke Young, Brookings Inst.).

This market distortion has led to a widespread phenomenon of surprise billing. More than 20 percent of in-network emergency department visits involve care from out-of-network physicians. *See* Zack Cooper et al., *Out-of-Network Billing and Negotiated Payments for Hospital-Based Physicians*, 39 HEALTH AFFAIRS 24, 24 (Jan. 2020). Similarly, elective surgeries, even at in-network facilities, result in an out-of-network bill from providers of ancillary services in more than 20 percent of cases. *See* Karan R. Chhabra et al., *Out-of-Network Bills for Privately Insured Patients Undergoing Elective Surgery with In-Network Primary Surgeons and Facilities*, 323 JAMA 538, 540 (2020).

Before the enactment of the No Surprises Act, this phenomenon of out-of-network billing had been rapidly growing, “becoming more common and potentially more costly in both the emergency department and inpatient settings.” Eric C. Sun et al., *Assessment of Out-of-Network Billing for Privately Insured Patients Receiving Care in In-Network Hospitals*, 179 JAMA INTERN. MED. 1543, 1544 (2019). From 2010 to 2016, “the incidence of out-of-network billing increased from 32.3% to 42.8% of emergency department visits, and the mean potential liability to patients increased from \$220 to \$628. For inpatient admissions, the incidence of out-of-network billing increased from 26.3% to 42.0%, and the mean potential liability to patients increased from \$804 to \$2040.” *Id.*

One factor leading to the recent explosion in out-of-network billing practices has been the increasing participation of private equity groups in the health care market through the acquisition of physician practices. *See Requirements Related to Surprise Billing: Part II*, 86 Fed. Reg. 55,980, 56,046 (Oct. 7, 2021) (citing Jane M. Zhu et al., *Private Equity Acquisitions of Physician Medical Groups Across Specialties, 2013-2016*, 323 JAMA 663, 663-665 (2020)); *see also* Joseph D. Bruch et al., *Changes in Hospital Income, Use, and Quality Associated with Private Equity Acquisition*, 180 JAMA Intern. Med. 1428 (2020). These investors have made a conscious business decision to forgo joining insurance networks in order to be able to charge higher prices out of network. *See* Zack Cooper et al., *Surprise! Out-Of-Network Billing for Emergency Care in the United States*, 128 J. POL. ECON. 3626, 3672-3673 (2020). “Research on one large private equity-owned firm showed that when it entered a hospital network, out-of-network billing rates increased by more than 81 percentage points.” H.R. REP. NO. 116-615, pt. I, at 54.

This has led to unexpected, and devastating, medical bills for patients. “[B]alance bills can be

substantial. ... [T]he mean potential balance bills for anesthesiologists, pathologists, radiologists, and assistant surgeons were \$1,171, \$177, \$115, and \$7,420, respectively.” Cooper et al., 39 HEALTH AFFAIRS at 27; *see also* Erin L. Duffy et al., *Prevalence and Characteristics of Surprise Out-Of-Network Bills from Professionals in Ambulatory Surgery Centers*, 39 HEALTH AFFAIRS 783, 785 (2020) (finding 81 percent increase in average amounts of surprise bills at ambulatory surgical centers from 2014 to 2017). “Given that nearly half of individuals in the US do not have the liquidity to pay an unexpected \$400 expense without taking on debt, these out-of-network bills can be financially devastating to a large share of the population and should be a major policy concern.” Cooper et al., 128 J. POL. ECON. at 3627.

Even these average figures understate the devastating effect surprise bills have had on some patients. For example, patients have faced a \$7,924 surprise bill after emergency jaw surgery; a \$20,243 surprise bill for emergency care for a bike crash; and a \$27,660 bill after being hit by a public bus. Sarah Kliff, *Surprise Medical Bills, the High Cost of Emergency Department Care, and the Effects on Patients*, 2019 JAMA INTERN. MED. 1457, 1457 (2019). “[A]mong the most shocking [examples of balance billing abuses] was a spinal surgery patient who received a bill of \$101,000 despite having confirmed that her surgeon was in-network.” H.R. REP. NO. 116-615, pt. I, at 52.

Beyond these financial consequences in individual cases, the market distortion created by surprise billing has had the broader effect of driving up health care costs for all parties. This is because “the ability to bill out of network allows [emergency department] physicians to be paid in-network rates that are significantly higher than those paid to other specialists who cannot readily bill out of network. These higher payments get passed along to all consumers (including those who do not even access care) in the form of higher insurance premiums.” Cooper et al., 39 HEALTH AFFAIRS at 24. For example, anesthesiologists (who have generally been able to remain out-of-network and balance bill patients) have been able to command in-network payment at rates more than twice as high as orthopedists (who have generally lacked that ability), when their payment rates are measured as a percentage of Medicare reimbursement rates. *See id.* at 26.

Likewise, emergency room physicians have been able to command higher in-network payment

rates, a phenomenon “caused not by supply or demand, but rather by the ability to ‘ambush’ the patient.” Cooper et al., 128 J. POL. ECON. at 3628. Because emergency department care is so common, this practice “raise[s] overall health spending.” *Id.* This has resulted in “commercial health insurance premiums as much as 5% higher than they otherwise would be in the absence of this market failure,” Duffy et al., 26 AM. J. MANAGED CARE at 403, placing a financial burden “on employer plan sponsors as well as individuals.” *Examining Surprise Billing: Protecting Patients from Financial Pain: Hearing Before the H. Comm. on Educ. and Labor, Subcomm. on Health, Employment, Labor and Pensions*, 116th Cong. 39 (2019) (statement of Ilyse Schuman, Senior Vice-President, American Benefits Council).

II. Congress Enacted the No Surprises Act to Protect Patients from Surprise Billing Practices and to Control Health Care Costs.

To address these surprise billing practices and to rein in the cost of health care, Congress enacted the No Surprises Act in December 2020. Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, div. BB, tit. I, 134 Stat. 1182, 2758-2890 (2020). Beginning on January 1, 2022, the Act protects insured patients from unexpected liabilities arising from the most common forms of balance billing. If an insured patient receives emergency care, or if he or she receives care that is scheduled at certain types of in-network facilities, health care providers are generally prohibited (absent, in certain circumstances, the patient’s consent) from balance billing the patient for any part of his or her care that is furnished by an out-of-network practitioner. *See* 42 U.S.C. §§ 300gg-131, 300gg-132.¹ Likewise, the patient’s cost-sharing responsibilities for out-of-network services may not exceed his or her financial responsibilities “that would apply if such services were provided by a participating provider or a participating emergency facility.” 42 U.S.C. § 300gg-111(a)(1)(C)(ii), (b)(1)(A). For example, if the patient’s health insurance policy would require him or her to pay coinsurance of 20% of the cost

¹ The Act makes parallel amendments to the Public Health Service Act (“PHSA”) (administered by the Department of Health and Human Services (“HHS”)), the Employee Retirement Income Security Act (“ERISA”) (administered by the Department of Labor), and the Internal Revenue Code (administered by the Department of the Treasury). In addition, the Act requires the Office of Personnel Management to ensure that its contracts with Federal Employees Health Benefits Program carriers require compliance with applicable provisions in the same manner as group health plans and health insurance issuers. 5 U.S.C. § 8902(p). For ease of reference, except where otherwise noted, this brief cites only to the Act’s amendments to the PHSA.

of an in-network service, the patient's responsibility for any out-of-network service would be limited to the same 20% co-insurance. *Id.* § 300gg-111(a)(1)(C)(ii), (iii); (b)(1)(A), (B).

More specifically, the patient's cost-sharing responsibilities are calculated "as if the total amount that would have been charged for such services by such participating provider or participating emergency facility were equal to the recognized amount[.]" *Id.* § 300gg-111(a)(1)(C)(ii), (b)(1)(B). The "recognized amount" is a term of art under the statute. If an All-Payer Model Agreement is in place in a given State, or a specified State law applies with respect to a particular medical service, then the Agreement or the State law will determine the recognized amount.² Otherwise, the "recognized amount" is the "qualifying payment amount (as defined in subparagraph (E)) for such year and determined in accordance with rulemaking described in paragraph (2)(B)) for such item or service." *Id.* § 300gg-111(a)(3)(H)(ii); *see also id.* § 300gg-111(a)(2)(B) (directing the Departments to issue rules by July 1, 2021 that set the methodology for determining the qualifying payment amount).

The "qualifying payment amount," in turn, is also a statutory term of art. It is generally defined, for a given item or service and for a given insurer, as "the median of the contracted rates recognized" by the group health plan or insurer, measured with respect to the payment rates for "the same or a similar item or service that is provided by a provider in the same or similar specialty and provided in the geographic region in which the item or service is furnished," under all the plans offered by that insurer in a given insurance market. *Id.* § 300gg-111(a)(3)(E)(i)(I). The qualifying payment amount is based on the insurer's or group health plan's calculation of the median for its plans as of January 31, 2019; this amount is subject to an inflation adjustment under a methodology to be established by the Departments. *Id.* The statute thus textually treats the "qualifying payment amount," calculated in this manner, as a reasonable proxy for what the in-network payment rate would have been for a given out-of-network service, for the purposes of calculating an insured patient's cost-sharing responsibilities.

² Texas has enacted a State law that governs patient's cost-sharing responsibilities for out-of-network services and the arbitration process for disputes between providers and insurers over payments for such services. Tex. Ins. Code Ann. § 751.001 *et seq.* The State law does not apply to group health plans that are subject to ERISA. *See* 86 Fed. Reg. 55,980, 56,091 (Oct. 7, 2021).

In addition to setting the rules to determine a patient's payment obligations for a particular out-of-network medical service, the Act also establishes a procedure to resolve disputes between health care providers and insurers over the amount of payment for such a service, in which the "qualifying payment amount" again plays a central role. The Act specifies that an insurer will issue an initial payment, or notice of a denial of payment, to a provider within 30 calendar days after the provider submits a bill to it for an out-of-network service. *Id.* § 300gg-111(a)(1)(C)(iv), (b)(1)(C). If the provider is not satisfied with this determination, it may initiate a 30-day period of open negotiation with the insurer over the claim. *Id.* § 300gg-111(c)(1)(A). If those negotiations do not resolve the dispute, the parties may then proceed to an independent dispute resolution process. *Id.* § 300gg-111(c)(1)(B).

The Act specifies that the Departments "shall establish by regulation," no later than December 27, 2021, "one independent dispute resolution process ... under which" an arbitrator, known in the statute as a "certified IDR entity," "determines, ... in accordance with the succeeding provisions of this subsection, the amount of payment under the plan or coverage for such item or service furnished by such provider or facility." *Id.* § 300gg-111(c)(2)(A). The Act further instructs the Departments to "establish a process" to certify arbitrators, *id.* § 300gg-111(c)(4)(A), under which such an entity "meets such other requirements as determined appropriate by the Secretary," *id.* § 300gg-111(c)(4)(A)(vii). The Departments are also instructed to "provide for a method" under which the parties to a dispute either jointly select an arbitrator or defer to the Departments' selection, *id.* § 300gg-111(c)(4)(F).

The Act establishes a system of "baseball" arbitration under which both the provider and the insurer or group health plan will each submit a proposed payment amount, with an explanation, and the arbitrator will select one or the other offer as the amount of payment for the item or service that is in dispute, "taking into account the considerations specified in subparagraph (C)." *Id.* § 300gg-111(c)(5)(A)(i). Subparagraph (C) begins by instructing the arbitrator to consider "the qualifying payment amounts (as defined in subsection (a)(3)(E)) for the applicable year for items or services that are comparable to the qualified IDR item or service and that are furnished in the same geographic region (as defined by the Secretary for purposes of such subsection) as such qualified IDR item or

service.” *Id.* § 300gg-111(c)(5)(C)(i)(I).

Subparagraph (C) then goes on to set forth several examples of “additional information” and “additional circumstances” for the arbitrator to consider. *Id.* § 300gg-111(c)(5)(C)(i)(II), (C)(ii). The “additional circumstances” include: the provider’s level of training, experience, and quality and outcomes measurements; the market share of the provider or of the insurer; the acuity of the individual receiving the medical service, or the complexity of that service; the provider’s teaching status, case mix, and scope of services; and a demonstration of the provider’s or the insurer’s good faith efforts to enter into network agreements for the service, or the lack of such efforts. *Id.* The “additional information” for the arbitrator to consider includes any “information as requested by the IDR entity relating to such offer,” and “any information relating to such offer submitted by either party.” *Id.* § 300gg-111(c)(5)(B)(i)(II), (B)(ii). The arbitrator is prohibited from considering the provider’s usual and customary charges for an item or service, the amount that the provider would have billed for the item or service in the absence of the Act, or the reimbursement rates for the item or service under the Medicare or Medicaid programs. *Id.* § 300gg-111(c)(5)(D). The arbitrator’s decision is binding on the parties, and is not subject to judicial review, except under the circumstances described in the Federal Arbitration Act. *Id.* § 300gg-111(c)(5)(E).

The Act requires the Departments to publish a report for each calendar quarter that states, among other things, “the number of times the payment amount determined (or agreed to) under this subsection exceeds the qualifying payment amount, specified by items and services,” and for each dispute decided by an arbitrator, “the amount of such offer so selected expressed as a percentage of the qualifying payment amount.” *Id.* § 300gg-111(c)(7)(A)(v), (B)(iv). The arbitrator shall submit such information to the Departments as they determine necessary to enable them to carry out these publication requirements. *Id.* § 300gg-111(c)(7)(C).

Congress thus selected an approach to the resolution of provider-insurer payment disputes that was “designed to reduce premiums and the deficit.” H.R. REP. NO. 116-615, at 58; *see also id.* at 48 (IDR process is structured “to reduce costs for patients and prevent inflationary effects on health care costs”). The Act would not succeed in this goal, however, if arbitrations were to result routinely

in payments greater than median in-network payment amounts; such a process would *increase* both federal deficits and health insurance premiums. *See id.* at 57. The Congressional Budget Office (“CBO”) scored the Act on the understanding that Congress had avoided this pitfall, finding that the Act’s arbitration procedures will result in “smaller payments to some providers [that] would reduce premiums by between 0.5 percent and 1 percent. Lower costs for health insurance would reduce federal deficits because the federal government subsidizes most private insurance through tax preferences for employment-based coverage and through the health insurance marketplaces established under the Affordable Care Act.” CBO, *Estimate for Divisions O Through FF H.R. 133, Consolidated Appropriations Act, 2021, Public Law 116-260 Enacted on December 27, 2020* at 3 (Jan. 14, 2021).³ In total, the Act is expected to reduce the deficit by \$16.8 billion, over ten years. *Id.* at 7.

III. The Departments Issued Rules to Implement the Act’s Framework to Protect Patients and to Control Health Care Costs.

As noted above, Congress instructed the Departments to issue one set of rules no later than July 1, 2021, addressing the No Surprises Act’s patient protections, and to issue a second set of rules no later than December 27, 2021, addressing the procedures for resolving payment disputes. 42 U.S.C. §§ 300gg-111(a)(2)(B), (c)(2)(A).

The Departments released their first set of interim final rules on July 1, 2021. *Requirements Related to Surprise Billing: Part I*, 86 Fed. Reg. 36,872 (July 13, 2021). Those rules implemented the Act’s provisions that prohibit providers from balance billing their patients for out-of-network medical services in certain situations; limit patients’ cost-sharing responsibilities for these services; require providers to make disclosures to patients of federal and state protections against balance billing; codify certain additional patient protections; set forth complaint processes with respect to violations of the Act’s balance billing and out-of-network cost sharing protections; and set the methodology for

³ *See also* CBO, *H.R. 5826, the Consumer Protections Against Surprise Medical Bills Act of 2020, as Introduced on February 10, 2020: Estimated Budgetary Effects* at 1 (Feb. 11, 2020) (“[Under] H.R. 5826 ..., dispute resolution entities would be instructed to look to the health plan’s median payment rate for in-network rate care. ... [U]nder the bill, ... average payment rates for both in- and out-of-network care would move toward the median in-network rate, which tends to be lower than average rates. CBO and JCT estimate that in most affected markets in most years, lower payments to some providers would reduce premiums by between 0.5 percent and 1 percent,” also lowering federal deficits).

determining the qualifying payment amount. *See id.* at 36,876. Those rules are not challenged here.

The Departments released a second set of interim final rules on September 30, 2021. *Requirements Related to Surprise Billing: Part II*, 86 Fed. Reg. 55,980 (Oct. 7, 2021). These rules implemented the Act's provisions requiring health care providers to furnish good-faith estimates of the cost of medical services to uninsured individuals; establishing a procedure for these individuals to dispute bills that exceed these good-faith estimates; extending the Affordable Care Act's external review requirements to adverse benefit determinations under the Act's surprise billing provisions; and clarifying that carriers under the Federal Employees Health Benefits Program generally are subject to the Act's terms. *See id.* at 55,984-55,987.

These rules also exercise Congress's delegation of authority to the Departments to "establish by regulation one independent dispute resolution process," 42 U.S.C. § 300gg-111(c)(2)(A), for the resolution of disputes between providers, group health plans, and insurers over the amount of payment for certain out-of-network services. In particular, the rules set forth procedures for arbitrators to be certified, and for providers, group health plans, and insurers to invoke the Act's independent dispute resolution system. *See* 86 Fed. Reg. at 55,985. The interim final rules also address the factors that the arbitrator should consider in deciding between the competing offers to be submitted by providers and insurers and setting the out-of-network payment amount for a given medical service.

The arbitrator is instructed to "[s]elect as the out-of-network rate ... one of the offers submitted [by the provider and the insurer], taking into account the considerations specified in paragraph (c)(4)(iii) of this section (as applied to the information provided by the parties pursuant to paragraph (c)(4)(i) of this section)." 45 C.F.R. § 149.510(c)(4)(ii)(A).⁴ After taking these considerations into account, the arbitrator "must select the offer closest to the qualifying payment amount unless [it] determines that credible information submitted by either party under paragraph (c)(4)(i) clearly

⁴ The interim final rules set forth parallel regulations implemented by HHS, the Department of Labor, and the Department of the Treasury. For ease of reference, except where otherwise noted, this brief cites only to the HHS regulations.

demonstrates that the qualifying payment amount is materially different from the appropriate out-of-network rate, or if the offers are equally distant from the qualifying payment amount but in opposing directions.” *Id.*

The considerations that the rule instructs the arbitrator to take into account are: the qualifying payment amount; any information that the arbitrator requests the parties to submit, so long as that information is credible; and any additional information submitted by a party, provided that information is credible, relates to certain specified circumstances as described in the regulation, and “clearly demonstrate[s] that the qualifying payment amount is materially different from the appropriate out-of-network rate.” *Id.* § 149.510(c)(4)(iii)(C). Mirroring the statute, the rule describes these specified circumstances as (1) the provider’s level of training, experience, and quality and outcomes measurements; (2) the provider’s and the insurer’s relative market shares in the geographic region where the service was performed; (3) the acuity of the patient, or the complexity of the service; (4) the provider’s teaching status, case mix, and scope of services; and (5) the good faith efforts, or the lack thereof, by the provider or by the insurer to enter into in-network agreements for the service, and contracted rates, if any, for the service. *Id.* § 149.510(c)(4)(iii)(C). The arbitrator must also consider any “[a]dditional information submitted by a party,” so long as the information is credible, relates to the party’s offer, and does not include information on the factors that the arbitrator is prohibited from considering under the statute. *Id.* § 149.510(c)(4)(iii)(D).

For these purposes, the rule defines “credible information” as “information that upon critical analysis is worthy of belief and is trustworthy,” *id.* § 149.510(a)(2)(v), and “material difference” as “a substantial likelihood that a reasonable person with the training and qualifications of a certified IDR entity making a payment determination would consider the submitted information significant in determining the out-of-network rate and would view the information as showing that the qualifying payment amount is not the appropriate out-of-network rate,” *id.* § 149.510(a)(2)(viii).

In issuing the September rule, the Departments invoked their authority under 42 U.S.C. § 300gg-92 “to promulgate any interim final rules that they determine are necessary or appropriate to carry out the provisions” of the PHSA, ERISA, or the applicable provisions of the Internal Revenue

Code. 86 Fed. Reg. at 56,043.⁵ The Departments also determined that there was good cause under 5 U.S.C. § 553(b)(B) to issue the interim final rule before opening a period of notice-and-comment on the rule, given that a delay for a comment period “would not provide sufficient time for the regulated entities to implement the requirements” of the Act and the rule. *Id.* at 56,044.

IV. This Litigation is Brought.

The Plaintiffs, the Texas Medical Association (“TMA”) and Dr. Adam Corley, brought this suit to challenge the September rule’s provisions addressing the considerations the arbitrator should take into account in deciding the out-of-network payment amount. Compl., ECF No. 1. They contend that these provisions of the rule are unambiguously contrary to the statute, and that the Departments erred by issuing these provisions without first providing for a period of notice and comment. *Id.* ¶¶ 75-91.

TMA recites that its “members include Texas physicians who provide out-of-network services,” some of whom “provide out-of-network services covered by the [No Surprises Act],” Decl. of E. Linda Villarreal, ¶ 7, ECF No. 25-1, but it does not identify any of those members. It contends that the challenged portions of the rule “will systematically favor payors and reduce out-of-network reimbursement rates.” *Id.* ¶ 8. It does not elaborate, however, on what would cause these payment reductions, and it does not provide any examples of an association member who would see such a payment reduction under the rule.

Dr. Corley is an emergency room physician who practices medicine through Precision Emergency Physicians, PLLC. Decl. of Adam Corley, ¶¶ 2-3, ECF No. 25-2. He also owns a percentage of Hospitality Health ER, a freestanding emergency department. *Id.* ¶ 6. Hospitality Health ER is a corporate brand name; a second corporation, Galveston ER Operation, LLC, does business under that name. Decl. of Melanie Michaelson, Exs. A, B (filed with this memorandum). Dr. Corley is “reimbursed at an hourly rate for [his] emergency medical services.” Corley Decl. ¶ 4. Dr. Corley contends that he will treat some patients whose bills are subject to the arbitration procedures of the No Surprises Act. *Id.* ¶¶ 5, 7. He

⁵ The Departments of Labor and of the Treasury share this interim final rulemaking authority with HHS. 26 U.S.C. § 9833; 29 U.S.C. § 1191c. In addition, as noted above, 5 U.S.C. § 8902(p) directs OPM to ensure that carriers participating in the Federal Employees Health Benefits Program comply with applicable provisions of the No Surprises Act “in the same manner” as group health plans and health insurance issuers.

contends that the qualifying payment amount will “often” be below “fair market value for the services provided,” *id.* ¶ 8, and that the rule “will result in lower reimbursement rates” and will “harm[] [his] financial interests,” *id.* ¶¶ 9, 11, but he does not provide specific examples of a particular service for which he contends he would receive greater payments under a different arbitration rule.

STANDARD OF REVIEW

“As the party invoking federal jurisdiction, the plaintiffs bear the burden of demonstrating that they have standing.” *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2207 (2021). That burden “becomes gradually stricter as the parties proceed through the successive stages of the litigation.” *In re Deepwater Horizon*, 739 F.3d 790, 799 (5th Cir. 2014). “[A]t the summary judgment stage, such a party can no longer rest on mere allegations, but must set forth specific facts that adequately support their contention.” *California v. Texas*, 141 S. Ct. 2104, 2117 (2021).

When evaluating a challenge to an agency’s interpretation of a statute, a court should first ask “whether Congress has directly spoken to the precise question at issue.” *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842 (1984). If it has, “that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.” *Id.* at 842-43. Where Congress has not spoken directly to the issue at hand, the court should defer to the agency’s interpretation so long as it is “based on a permissible construction of the statute.” *Id.* at 843. That is true “even if the agency’s reading differs from what the court believes is the best statutory interpretation.” *Nat’l Cable & Telecomm. Ass’n v. Brand X Internet Servs.*, 545 U.S. 967, 980 (2005).

In evaluating an agency’s decision to issue a rulemaking without first providing for a period of notice and comment, the Fifth Circuit “us[es] the APA’s standard: agency action may be set aside if it is ‘arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.’” *United States v. Johnson*, 632 F.3d 912, 928 (5th Cir. 2011) (quoting 5 U.S.C. § 706(2)(A)). This standard is “narrow and highly deferential.” *Sierra Club v. U.S. Dep’t of Interior*, 990 F.3d 909, 913 (5th Cir. 2021). “[T]he court is not to substitute its judgment for that of the agency.” *Id.* (citation omitted). Rather, the court “consider[s] whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment.” *Id.* (citation omitted). In short, the arbitrary-and-capricious

standard simply “requires that agency action be reasonable and reasonably explained.” *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021).

ARGUMENT

I. THE PLAINTIFFS HAVE NOT SHOWN THAT THEY HAVE STANDING TO CHALLENGE THE RULE’S ARBITRATION PROCEDURES.

To prove Article III standing, the Plaintiffs must show that they have “(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision.” *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016); *see also Ortiz v. Am. Airlines, Inc.*, 5 F.4th 622, 628 (5th Cir. 2021). In particular, to show an injury in fact, they must prove that they have suffered “an invasion of a legally protected interest [that] is concrete and particularized and actual or imminent, not conjectural or hypothetical.” *Kitty Hawk Aircargo, Inc. v. Chao*, 418 F.3d 453, 459 (5th Cir. 2005). The Plaintiffs contend that they suffer an injury from the September rule’s description of the considerations that an arbitrator should take into account in setting the out-of-network payment amount. They have failed to meet their burden, for multiple reasons.

First, the Plaintiffs have offered only speculation and conclusory assertions that they will suffer any injury that is traceable to the rule. TMA contends, without elaboration, that the challenged portions of the rule “will systematically favor payors and reduce out-of-network reimbursement rates.” Villarreal Decl. ¶ 8. Dr. Corley, likewise, simply asserts that the rule generally “will result in lower reimbursement rates” and will “harm[] [his] financial interests.” Corley Decl. ¶¶ 9, 11. These unadorned assertions fall far short of the proof needed to support the Plaintiffs’ summary judgment motion.

At the summary judgment stage, the Plaintiffs must set forth “specific facts” in affidavits to support their claim of standing. *California v. Texas*, 141 S. Ct. at 2117; *see also Ortiz*, 5 F.4th at 628. This burden cannot be met by “a conclusory statement in [an] affidavit.” *Kitty Hawk Aircargo*, 418 F.3d at 459; *see also Lujan v. Nat’l Wildlife Fed’n*, 497 U.S. 871, 888 (1990) (a plaintiff may not meet its burden at summary judgment through “conclusory allegations of an affidavit”). The Plaintiffs simply do not provide sufficient detail to evaluate their claim that they are harmed by the rule, or that they would benefit if the rule were phrased differently. It is impossible to say on this record, for example, whether

a particular provider would need to resort to the Act's arbitration process at all, or, if they do so, whether an arbitrator would be more likely, under the Plaintiffs' preferred approach, to find that a provider's level of experience warrants a higher or a lower payment. *See* 42 U.S.C. § 300gg-111(c)(5)(C)(ii). The arbitrator might be more likely, under an alternative rule, to award a particular provider a lower payment if it found that the provider's market share warranted a smaller amount; that it had not made a good faith effort to enter into in-network agreements; or that any other factor counseled in favor of a payment reduction. *See id.*; *see also* 86 Fed. Reg. at 56,060 (noting that some providers may realize increased out-of-network payments under the rule). In the absence of "specific facts" demonstrating an actual, concrete, particularized injury, *Ortiz*, 5 F.4th at 628, the Plaintiffs have not met their burden to show an Article III case or controversy.

Second, TMA's allegations of injury suffer from an additional defect. The medical association asserts generally that its members provide out-of-network medical services that will be subject to the Act's independent dispute resolution process, Villarreal Decl. ¶ 7, yet it does not identify any of those members. But to demonstrate an injury in fact, an associational plaintiff must make "specific allegations establishing that at least one identified member ha[s] suffered or would suffer harm." *Summers v. Earth Island Inst.*, 555 U.S. 488, 498 (2009). The association cannot base its claim of standing solely on its "self-description of the activities of its members" or by contending that "there is a statistical probability that some of those members are threatened with concrete injury." *Id.* at 497; *see also Funeral Consumers All., Inc. v. Serv. Corp. Int'l*, 695 F.3d 330, 344 (5th Cir. 2012). TMA's vague reference to harms that might be suffered some day by some of its unnamed members, then, cannot support its claim to standing.

Third, Dr. Corley's affidavit demonstrates that he is not a proper plaintiff, either. He practices medicine through one corporation, Precision Emergency Physicians, PLLC. Corley Decl. ¶¶ 2-3. He also owns a percentage of Hospitality Health ER, a freestanding emergency department that is a corporate brand name for a second corporation, Galveston ER Operation, LLC. *Id.*, ¶ 6; Michaelson Decl., Exs. A, B. The "financial interests" that he alleges to be harmed by the rule are interests of one corporation or the other, not of Dr. Corley in his individual capacity. But it is well established that

“the proper party to bring a suit on behalf of a corporation is the corporation itself, acting through its directors or a majority of its shareholders.” *Daily Income Fund, Inc. v. Fox*, 464 U.S. 523, 542 (1984). An individual shareholder has no right to “initiat[e] actions to enforce the rights of the corporation.” *Franchise Tax Bd. v. Alcan Aluminium Ltd.*, 493 U.S. 331, 336 (1990); *see also Gregory v. Mitchell*, 634 F.2d 199, 202 (5th Cir. 1981) (stockholders cannot “maintain an action to redress an injury to the corporation even though the value of their stock is impaired as a result of the injury”). Dr. Corley thus lacks standing to challenge the rule on behalf of the corporate entities.⁶

II. THE RULE’S ARBITRATION PROCEDURES ARE CONSISTENT WITH THE NO SURPRISES ACT.

A. The Act Does Not Unambiguously Prohibit the Departments from Guiding the Discretion of Arbitrators.

The No Surprises Act instructs the Departments to “establish by regulation ... one independent dispute resolution process” for arbitrators to resolve payment disputes between providers and insurers involving out-of-network medical services. 42 U.S.C. § 300gg-111(c)(2)(A). The Departments fulfilled that responsibility by issuing the September rule, which comprehensively addresses the procedures for the parties to invoke the arbitration process, to select an arbitrator, and to present their offers and their respective positions to that arbitrator, so that he or she may select one of the two offers under a “baseball” arbitration process. *See* 45 C.F.R. § 149.510(c)(4)(ii)(A).

The rule directs the arbitrator, in making that decision, to “tak[e] into account” several considerations, namely, (1) the qualifying payment amount; (2) any information that the arbitrator requests the parties to submit, if that information is credible; (3) and any additional information submitted by a party, if the information is credible, relates to certain specified circumstances as described in the regulation, and “clearly demonstrate[s] that the qualifying payment amount is materially different from the appropriate out-of-network rate.” *Id.* § 149.510(c)(4)(ii)(A), (iii).

⁶ In a decision later reversed by the Supreme Court, the Fifth Circuit, sitting *en banc*, recognized that “[t]he APA does not abolish the shareholder-standing doctrine,” but reasoned that it limits that doctrine if a plaintiff is within the zone of interests of a statute designed to protect the interests of shareholders. *Collins v. Mnuchin*, 938 F.3d 553, 575 (5th Cir. 2019), *rev’d in part sub nom. Collins v. Yellen*, 141 S. Ct. 1761 (2021). The No Surprises Act is not designed to protect shareholder rights, so the narrow exception described in *Collins* has no application here.

The specified circumstances, in turn, are the specific qualitative factors that are listed in the Act itself, such as the provider's level of experience and the provider's and the insurer's relative market shares. *Id.* § 149.510(c)(4)(iii)(C). The arbitrator is also instructed to consider any "[a]dditional information submitted by a party," so long as the information is credible, relates to the party's offer, and does not include information on the factors that the arbitrator is prohibited from considering under the statute. *Id.* § 149.510(c)(4)(iii)(D).

After taking these considerations into account, the arbitrator "must select the offer closest to the qualifying payment amount unless [it] determines that credible information submitted by either party under paragraph (c)(4)(i) clearly demonstrates that the qualifying payment amount is materially different from the appropriate out-of-network rate, or if the offers are equally distant from the qualifying payment amount but in opposing directions." *Id.*

For these purposes, information is "credible" if "upon critical analysis [it] is worthy of belief and is trustworthy," *id.* § 149.510(a)(2)(v), and information shows a "material difference" if there is "a substantial likelihood that a reasonable person with the training and qualifications of a certified IDR entity making a payment determination would consider the submitted information significant in determining the out-of-network rate and would view the information as showing that the qualifying payment amount is not the appropriate out-of-network rate," *id.* § 149.510(a)(2)(viii).

Taking Section 149.510(c)(4)(ii) together with the regulatory definitions, the rule thus instructs the arbitrator to: (1) begin with the qualifying payment amount; (2) consider each of the additional factors identified in the statute and regulation, including "any additional information" that the arbitrator or a party may consider to be relevant; (3) apply his or her expertise to assess whether there is a "substantial likelihood" that the information would show that the qualifying payment amount is not the appropriate out-of-network rate; and, after completing that analysis, then (4) select one of the offers as the payment rate, with the offer that is closest to the qualifying payment amount being the offer selected, unless the arbitrator finds that the additional statutory factors point in favor of a different decision.

The Departments thus reasonably exercised their authority under the Act to establish an

independent dispute resolution process that sets forth these guidelines to structure the arbitrator's decision-making. Although the Plaintiffs fault the Departments for structuring this analysis to begin with the qualifying payment amount, the Act itself is structured in the same way. The statute lists the qualifying payment amount as the first factor for the arbitrator's consideration; the other factors listed for the arbitrator to consider are described as "additional circumstances" or "additional information." 42 U.S.C. § 300gg-111(c)(5)(C)(i)(II), (ii). These circumstances could only be "additional," of course, if there were some other circumstance already in place that they could be added to—here, the qualifying payment amount. The statute thus textually informs the reader that the analysis should begin with the qualifying payment amount, and then should move on to take into account the other statutory factors. See *In re Border Infrastructure Env't Litig.*, 915 F.3d 1213, 1223 (9th Cir. 2019) ("In simple terms, 'additional' means 'supplemental.'").

Moreover, "[i]t is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 666 (2007) (internal quotation marks omitted); see also *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 321 (2014) ("reasonable statutory interpretation must account for both the specific context in which ... language is used and the broader context of the statute as a whole" (internal quotation marks omitted)). The overall statutory scheme here shows Congress's expectation that—in the ordinary case at least—the qualifying payment amount is a proxy for the in-network price that a given medical service would command in a functional health care market. As noted above, the qualifying payment amount plays a central role in the Act's limitations on a patient's cost-sharing responsibilities for out-of-network care. Where the Act applies, the patient's cost-sharing obligation may not be greater than the requirement that would apply if such services were provided by a participating provider, 42 U.S.C. § 300gg-111(a)(1)(C)(i), (b)(1)(A), and must be calculated based on the "recognized amount," *id.* § 300gg-111(a)(1)(C)(ii), (b)(1)(B)—namely (with immaterial exceptions), the qualifying payment amount, *id.* § 300gg-111(a)(3)(H). The text of the statute thus equates the qualifying payment amount with the reasonable amount of payment for a given medical service.

What is more, many of the statutory factors would already have played a role in the calculation of the qualifying payment amount in the first place. Recall that this amount is generally defined, for any given medical service, as “the median of the contracted rates recognized” by the insurer, measured with respect to the payment rates for “the same or a similar item or service that is provided by a provider in the same or similar specialty and provided in the geographic region in which the item or service is furnished,” under all of the plans offered by that insurer in a given insurance market. *Id.* § 300gg-111(a)(3)(E)(i). The arm’s-length negotiations underlying these contracted rates, ordinarily, would have taken into account the typical provider’s level of training, experience, and quality. *Id.* § 300gg-111(c)(5)(C)(ii). Likewise, one would expect these negotiations to take into account the provider’s and the insurer’s market share in a given region; the parties’ negotiating histories; the typical acuity of patients receiving a service, or the complexity of that service; and any other particular features of providers, such as teaching status, that might be relevant in setting an arm’s-length price. *See id.*

Outliers are possible, of course. In any particular case, for example, a medical procedure might be abnormally complex (or unusually simple), or a provider might have an unusually dominant share of the market in a given region that allows it to improperly inflate its prices. The qualifying payment amount is a “median” amount, *id.* § 300gg-111(a)(3)(E)(i), and so might not reflect the appropriate payment amount in these unusual cases. But it can be expected to reflect—indeed, it textually is assigned the role of—the appropriate payment rate in the typical case. The rule thus properly instructs the arbitrator to consider whether there is a “substantial likelihood” that any factor might show that the qualifying payment amount is higher or lower than the appropriate out-of-network payment rate.

Indeed, it is difficult to imagine how the arbitrator could go about the decision-making process without starting with the qualifying payment amount. The arbitrator’s analysis begins with one number—the qualifying payment amount, *i.e.*, the median payment amount for the medical service in the geographic region where the service in question was performed. And it ends with another number—the payment amount for the service that is in dispute. What comes in between are a series of qualitative, not quantitative, factors. The clear implication is that Congress intended the arbitrator to consider these qualitative factors to determine whether a departure from the first number was

warranted in arriving at the second number. At all events, “there is no canon against using common sense in construing laws as saying what they obviously mean.” *Koons Buick Pontiac GMC, Inc. v. Nigh*, 543 U.S. 50, 63 (2004).

This common-sense understanding is confirmed when one considers the reporting obligations that Congress imposed on the Departments. They are to publish a report, each calendar quarter, that states the number of times the arbitrator determines a payment amount that is greater than the qualifying payment amount, 42 U.S.C. § 300gg-111(c)(7)(A)(5), and the amount of each payment award, expressed as a percentage of the qualifying payment amount, *id.* § 300gg-111(c)(7)(B)(iv). These reporting obligations are not mere technical details. Instead, Congress was focused on ensuring that the Act’s dispute resolution mechanism would “reduce premiums and the deficit.” H.R. REP. NO. 116-615, at 58. But if arbitrators were to systematically set out-of-network payment rates higher than the qualifying payment amount, “this could result in a potential increase in costs and premiums.” 86 Fed. Reg. at 56,060 (citing Loren Adler et al., *Understanding the No Surprises Act*, USC-Brookings Schaeffer Initiative for Health Policy (Feb. 4, 2021)); *see also* H.R. Rep. No. 116-615, at 57 (predicting “double digit billions” of dollars in increases in the federal deficit if the arbitration process were designed to increase payments systematically above median in-network rates). Congress thus set forth these reporting obligations so that it could carefully monitor whether the Act was working as intended, to bring out-of-network payments in line with payments negotiated in a free market for in-network reimbursement.

B. The Plaintiffs’ Contrary Arguments Are Premised on a Misreading of the Rule.

The Plaintiffs devote the lion’s share of their brief to an argument that “Congress clearly did not believe the QPA should be determinative for purposes of reimbursement.” Pls.’ MSJ at 19, ECF No. 25. But they are attacking a straw man of their own devising. The rule that the Departments actually published does not make the qualifying payment amount “determinative.” Instead, as discussed above, the rule instructs the arbitrator to begin with the qualifying payment amount, and then to consider each factor to determine if there is a “substantial likelihood” that the factor would be “significant” in showing that the appropriate out-of-network payment rate is different from the

median in-network payment rate for a given medical service. 45 C.F.R. § 149.510(a)(2)(viii). The rule thus leaves ample room for the arbitrator to apply his or her expertise to consider each of the factors that the parties bring to his or her attention.

The Plaintiffs' arguments lose force, then, when they are considered against the rule as it actually exists. They fault the Departments, for example, for purportedly violating a statutory command that "Congress required IDR entities to consider *each* factor in *every* case." Pls.' MSJ at 14 (emphasis in original), but the rule itself requires just that. *See* 45 C.F.R. § 149.510(c)(4)(ii)(A) (instructing the arbitrator to "tak[e] into account" each of the statutory considerations). They further fault the Departments for creating a "rebuttable presumption," noting that this phrase does not appear in the Act itself. Pls.' MSJ at 2. But that phrase doesn't come up in the regulatory text either; instead, the Departments used that phrase in the preamble as a reasonable shorthand to describe the Act's decision-making process, which begins with a review of the qualifying payment amount and then adds the consideration of certain "additional" factors, which the arbitrator may use for a upward or downward departure if he or she finds those factors to be significant to the payment determination. *Cf. AT&T Corp. v. FCC*, 970 F.3d 344, 351 (D.C. Cir. 2020) (agency statements in preamble generally are not final agency action).

The Plaintiffs further protest that, "[i]f Congress had intended the QPA to be given presumptive effect, it would have said so." Pls.' MSJ at 22. Again, this misdescribes the September rule. But, in any event, "the mere possibility of clearer phrasing" cannot defeat the Departments' reasonable understanding of the Act. *Caraco Pharm. Labs, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 416 (2012). This "is especially so because we can turn this form of argument back around on" the Plaintiffs. *Id.* Congress also could have expressly adopted the Plaintiffs' preferred formulation—that is, a process under which the arbitrator was left with discretion to assign any factor any weight he or she wished to assign—had it wanted to do so. It didn't, and so the reader is left with the text, the structure, and the purpose of the statute that Congress actually did enact. As explained above, each of these considerations point in favor of reading the Act to direct arbitrators to begin their analysis with the qualifying payment amount. At the very least, the Act does not foreclose this reading, and

the Departments reasonably interpreted the Act to so require.

The Plaintiffs also note that Congress, elsewhere in the Consolidated Appropriations Act, used the phrase “rebuttable presumption,” and they assert that the absence of that phrase in the No Surprises Act must therefore be an expression of Congress’s intent to discount the evidentiary value of the qualifying payment amount. Pls.’ MSJ at 15 (citing *Russello v. United States*, 464 U.S. 16 (1983), and Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, Div. Q, tit. II, subtit. B, § 226, 134 Stat. 1182, 2208 (2020)). But the *Russello* canon is “inapplicable” to “omnibus legislation.” *Restrepo v. Att’y Gen.*, 617 F.3d 787, 793-94 (3d Cir. 2010). The Consolidated Appropriations Act, like many similar omnibus statutes, stitched together 32 separate bills, each with their own drafting histories, and with “a broad spectrum of congressional intent in play across the distinct statutes that comprise the larger enactment.” *Id.* at 794. That Congress used one phrase in setting standards for trademark infringement in Division Q of the Act, then, says nothing at all about its intent in enacting patient protections from surprise billing in Division BB. *See also* Abbe R. Gluck & Lisa Schultz Bressman, *Statutory Interpretation from the Inside—an Empirical Study of Congressional Drafting, Delegation, and the Canons: Part I*, 65 STAN. L. REV. 901, 936 (2013) (noting that Congressional staffers accord no significance to inconsistent usage of terms in different provisions of an omnibus bill).

The Plaintiffs next lean on case law that leaves it to a federal agency’s discretion to decide how to weigh a set of statutory factors. Pls.’ MSJ at 16. From these cases, the Plaintiffs intuit that Congress must have left the statutory factors to the *arbitrators’* unconstrained discretion to weigh. But each of the cases that the Plaintiffs cite involves deference to the *Departments’* treatment of a set of statutory factors. *See New York v. Reilly*, 969 F.2d 1147, 1150 (D.C. Cir. 1992) (deferring to EPA’s analysis of Clean Air Act factors); *Cent. Vt. Ry., Inc. v. ICC*, 711 F.2d 331, 336 (D.C. Cir. 1983); *Ramirez v. ICE*, 471 F. Supp. 3d 88, 176 (D.D.C. 2020). Thus, if there was a gap to fill in the Act as to how to treat the various factors going into setting out-of-network payment amounts, the job of filling that gap belongs to the Departments that are charged with administering the Act, not independent, private arbitrators. In any event, as even one of the Plaintiffs’ cited cases notes, Congress can “prescribe a structure” under which an agency is to address competing considerations, *Ramirez*, 471 F. Supp. 3d at

176, and one way it can do so is by setting forth a sequence in which the agency is to address various factors, *id.* at 177. Congress did just that in enacting the No Surprises Act.

It is implausible that Congress intended to enact the Plaintiffs’ alternative approach, in which private arbitrators would enjoy virtually unfettered discretion to weigh any of the statutory factors in any way they choose. Recall that two of the factors for the arbitrator to consider are any “information as requested by the certified IDR entity relating to such offer,” and “any information relating to such offer submitted by either party.” 42 U.S.C. § 300gg-111(c)(5)(B), (C)(i)(II). Under the Plaintiffs’ approach, then, the arbitrator would be free to take essentially any information it wishes—either information that it requests one or both parties to provide, or information that either party takes it upon itself to furnish—accord that information dispositive weight, and then decide as it wishes. Congress is unlikely to have intended such a free-for-all. *Cf. Sunshine Anthracite Coal Co. v. Adkins*, 310 U.S. 381, 399 (1940) (applying the private non-delegation doctrine to prohibit a standardless delegation of authority to a private entity without supervision by a federal agency).

The Plaintiffs also refer to alternative versions of surprise-billing legislation that were under consideration in Congress. Pls.’ MSJ at 17. They note that Congress rejected bills that would have set the qualifying payment amount as the un rebuttable benchmark for out-of-network reimbursement. But that doesn’t describe the Departments’ rule. As noted above, the rule leaves ample room for arbitrators to depart from the qualifying payment amount when they find a “substantial likelihood” that evidence is “significant” in showing that the qualifying payment amount is not the appropriate out-of-network payment rate for a particular service. And, in any event, Congress also considered and rejected bills that would have adopted the Plaintiffs’ preferred approach of a standardless delegation of authority to private arbitrators to set payment rates at any level they choose. *See* S. 1266, 116th Cong. (2019); H.R. 4223, 116th Cong. (2019). The Plaintiffs’ “argument highlights the perils of relying on the fate of prior bills to divine the meaning of enacted legislation. ‘A bill can be proposed for any number of reasons, and it can be rejected for just as many others.’” *Caraco Pharm. Labs.*, 566 U.S. at 422 (quoting *Solid Waste Agency of N. Cook Cty. v. Army Corps of Eng’rs*, 531 U.S. 159, 170 (2001)).

Finally, the Plaintiffs invoke the maxim that Congress doesn’t hide elephants in mouseholes.

Pls.’ MSJ at 17. But if the qualifying payment amount is an elephant in the statute, it is an elephant that is standing in an open field. The qualifying payment amount is a central feature of the No Surprises Act. The Act sets forth detailed rules to ensure a precise calculation of the qualifying payment amount to ensure that a meaningful comparison is drawn among payment rates for comparable medical services, within the same geographic region, and within the same insurance market. *See* 42 U.S.C. § 300gg-111(a)(3)(E). The qualifying payment amount—the median in-network price for the medical service, calculated in this way—is deemed to be the reasonable rate of payment in calculating the patient’s cost-sharing obligation for out-of-network care. *See id.* § 300gg-111(a)(3)(H). And the same amount is front and center in the process for resolving provider-insurer payment disputes. *See id.* § 300gg-111(c)(5)(C)(i). Congress would not have gone to the trouble to set forth the calculation of the qualifying payment amount in minute detail, only to render its handiwork irrelevant to the arbitration process by giving the arbitrator free rein to ignore that calculation.

C. The Departments Are Entitled to *Chevron* Deference.

As noted above, the Departments issued the September rule to fulfill Congress’s instructions that they “establish by regulation ... one independent dispute resolution process” for the resolution of out-of-network payment disputes. The Departments’ exercise of this rulemaking authority is thus entitled to deference under *Chevron*. And the rule easily survives under this deferential standard. The best reading of the No Surprises Act provides for the qualifying payment amount to play a central role in the arbitrator’s decision-making process. At the very least, this is a permissible reading of the statute, and the Departments reasonably resolved any statutory doubt in favor of a reading that furthers the statute’s goal of lowering health care costs.

The Plaintiffs contend that *Chevron* does not apply here because the Departments did not expressly state that they were exercising their substantive rulemaking authority. Pl.’s MSJ at 21. This argument is difficult to understand. If the September rule was not an exercise of the Departments’ authority to establish one independent dispute resolution process, what was it? The preamble to the rule tracks the statute to declare that, “[i]n order to implement the Federal IDR provisions under [42 U.S.C. § 300gg-111(c)] ... , these interim final rules establish a Federal IDR process that [providers

and insurers] may use following the end of an unsuccessful open negotiation period to determine the out-of-network rate for certain services.” 86 Fed. Reg. at 55,984. Likewise, the rules invoke 42 U.S.C. § 300gg-111 in amending the Code of Federal Regulations, *see* 86 Fed. Reg. at 56,124, and those amendments establish that the “basis and scope” for part 149 of title 45 of the Code (which includes the regulations on the IDR decision-making procedures that the plaintiffs challenge here) is, in relevant part, for the “establish[ment of] an independent dispute resolution process, and standards for certifying independent dispute resolution entities.” 45 C.F.R. § 149.10(b).⁷ The Departments thus plainly understood which statutory authorities they were using to create the arbitration process. *See SoundExchange, Inc. v. Copyright Royalty Bd.*, 904 F.3d 41, 54-55 (D.C. Cir. 2018) (rejecting a “‘magic words’ requirement” for the exercise of rulemaking authority).

The Plaintiffs also contend, Pls.’ MSJ at 21, that *Chevron* could not apply because the Departments stated that they were “of the view that the best interpretation” of the Act’s arbitration procedures was the one expressed in the rule, 86 Fed. Reg. at 55,996. In the Plaintiffs’ view, this discussion of an “interpretation” could not have been part of an exercise of substantive rulemaking authority. But the very point of *Chevron* is that, where Congress has delegated authority to an agency to administer a statute (as it has done here), “[s]tatutory ambiguities will be resolved, within the bounds of reasonable interpretation, not by the courts but by the administering agency.” *City of Arlington v. FCC*, 569 U.S. 290, 296 (2013).

The Plaintiffs go further to contend that the Departments have no substantive rulemaking authority at all. Pls.’ MSJ at 21-22 (citing *Pharm. Res. & Mfrs. of Am. v. HHS*, 43 F. Supp. 3d 28, 37-39 (D.D.C. 2014) (“*PhRMA*”). That case, however, involved a rule that did not fall within any of the agency’s grants of rulemaking authority. Here, by contrast, Congress has specifically delegated to the Departments the authority to establish the arbitration process under 42 U.S.C. § 300gg-111(c). Under *Chevron*, that delegation of authority empowers the Departments to resolve ambiguities as to which

⁷ *See also* 86 Fed. Reg. at 56,099, 56,110 (invoking the Department of the Treasury’s and the Department of Labor’s statutory authorities); 26 C.F.R. § 54.9816-1T(b) (basis and scope of parallel Treasury regulations); 29 C.F.R. § 716-1(b) (basis and scope of parallel Labor regulations).

arbitration rules would be “in accordance with” the remainder of that paragraph, *id.* § 300gg-111(c)(2)(A), including that paragraph’s discussion of the considerations for the arbitrator to take into account in setting an out-of-network payment amount, *id.* § 300gg-111(c)(5). Deference is thus owed to the Departments’ interpretation of those considerations. *See City of Arlington*, 569 U.S. at 296-97. Presumably in recognition of this legal principle, TMA submitted a comment in advance of the September rulemaking that “urge[d] the Departments” to “[r]equire the IDR entity ... *not* to weigh the QPA more than any other submitted information when picking a party’s offer.” Letter from E. Linda Villarreal, President, Tex. Med. Ass’n, et al., to Xavier Becerra, Secretary, U.S. Dep’t of Health & Human Servs., et al., at 16 (Sept. 7, 2021) (“TMA Comment”) (emphasis in original). TMA’s acknowledgment of the Departments’ rulemaking authority in its comment precludes it from “revers[ing] course” to deny that authority here. *S. Coast Air Quality Mgmt. Dist. v. EPA*, 472 F.3d 882, 892 (D.C. Cir. 2006).⁸

Finally, the Plaintiffs have not disputed that, *if* the statute gives the Departments the authority to frame the factors that arbitrators must consider, such that *Chevron* deference applies, then the rule is reasonable and satisfies Step Two of the *Chevron* analysis. And indeed, the rule plainly satisfies that deferential inquiry. The rule furthers the Congressional purpose for the Act’s independent dispute resolution mechanism to “reduce premiums and the deficit,” H.R. REP. NO. 116-615, at 58; a goal that could only be accomplished if that mechanism were to be structured to focus the arbitrator’s decision-making initially around the qualifying payment amount, *see id.* at 57; *see also* 86 Fed. Reg. at 55,996, 56,061. The rule also promotes predictability and regularity in the arbitration process. This is an important goal in its own right; each arbitration will carry with it its own transaction costs, and patients ultimately bear those costs in the form of increased premiums. A rule that generally promotes the predictability of arbitration outcomes will thus encourage earlier settlements and help to lower

⁸ The Plaintiffs simultaneously insist that the Departments must have issued an interpretive rule, Pls.’ MSJ at 20-23, and that the Departments lacked good cause to do so without first providing a period of notice and comment, *id.* at 23-30. If the Plaintiffs were right in their first argument, there would be no need to consider whether the Departments had good cause to issue the rule. Interpretive rules are exempt from the APA’s notice-and-comment requirements. 5 U.S.C. § 553(b)(A).

premiums. *See* 86 Fed. Reg. at 55,996. And, perhaps most fundamentally, the rule will address the market distortion caused by surprise billing practices, by diminishing the discrepancy between out-of-network payments for medical services and the in-network payments for the same services that are negotiated at arm's length in a free market. *See id.*

III. THE DEPARTMENTS WERE NOT REQUIRED TO ISSUE THE RULE THROUGH NOTICE-AND-COMMENT RULEMAKING.

A. The Governing Statutes Authorize the Departments to Issue Interim Final Rules as They Deem to Be Appropriate.

An agency ordinarily is required to publish a notice of proposed rulemaking, and to provide for a period of public comment, before issuing a substantive rule. *See* 5 U.S.C. § 553(b), (c). The Plaintiffs contend that the Departments erred by issuing the September rule without first providing for notice and comment. But these procedures are not required where Congress has “expressly” authorized agencies to engage in rulemaking through other processes, 5 U.S.C. § 559, and Congress has done so here.

An agency may forgo notice and comment, and instead issue an interim final rule, when Congress sets forth its “clear intent that APA notice and comment procedures need not be followed.” *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1237 (D.C. Cir. 1994); *see also Asiana Airlines v. FAA*, 134 F.3d 393, 397-98 (D.C. Cir. 1998); *Nat’l Women, Infants, & Children Grocers Ass’n v. Food & Nutrition Serv.*, 416 F. Supp. 2d 92, 105 (D.D.C. 2006) (statute providing that “[t]he Secretary may promulgate interim final regulations” “granted the [agency] some discretion to issue an interim rule without first providing notice and comment in order to ensure that a rule was in place by” a statute’s effective date). This is the case here.

The No Surprises Act amends the PHSA, ERISA, and the Internal Revenue Code. Each of these statutes authorizes the Secretary of each of the Departments to “promulgate any interim final rules as the Secretary determines are appropriate to carry out this subchapter,” 42 U.S.C. § 300gg-92; *see also* 26 U.S.C. § 9833; 29 U.S.C. § 1191c, and the Departments found it to be appropriate to issue interim final rules so as to allow regulated parties to prepare for the Act’s new legal regime. The

statutory authorization to issue interim final rules as the Departments “determine[] are appropriate” is an express grant of authority to issue rules without an advance period of public notice and comment, and to do so applying a standard that is different from the ordinary APA standards for interim final rules. *Cf. Kisor v. Wilkie*, 139 S. Ct. 2400, 2448-49 (2019) (Kavanaugh, J., concurring) (“[S]ome cases involve regulations [or, here, statutes] that employ broad and open-ended terms like ‘reasonable,’ ‘appropriate,’ ‘feasible,’ or ‘practicable.’ Those kinds of terms afford agencies broad policy discretion, and courts allow an agency to reasonably exercise its discretion to choose among the options allowed by the text of the rule [or, here, statute].”).

The Departments recognize that some out-of-circuit authority has reasoned that 42 U.S.C. § 300gg-92 does not authorize a departure from ordinary APA rulemaking procedures. *See Pennsylvania v. President*, 930 F.3d 543, 566 (3d Cir. 2019), *rev’d*, 140 S. Ct. 2367 (2020); *California v. Azar*, 911 F.3d 558, 578 (9th Cir. 2018). These cases, however, failed to account for the point that the Departments already had the authority under the APA to issue interim final rules even in the absence of Section 300gg-92. The specific grant of authority to the Departments to issue interim final rules as they “determine[] are appropriate” adopts a standard that is different from the ordinary APA procedures. Otherwise, Section 300gg-92 would be mere surplusage, an outcome contrary to the canons of statutory construction. *See Duncan v. Walker*, 533 U.S. 167, 174 (2001) (noting the “cardinal principle of statutory construction” that language should not be rendered “superfluous, void, or insignificant”).

Moreover, the generally understood meaning of the term “interim final rule” when Section 300gg-92 was enacted in 1996 was, as it is now, a rule issued without notice and comment. In 1995, for example, the Administrative Conference of the United States published recommendations explaining that agencies “commonly” use the term “‘interim final rulemaking’ to describe the issuance of a final rule *without prior notice and comment*, but with a post-promulgation opportunity for comment.” 60 Fed. Reg. 43,108, 43,111 (Aug. 18, 1995) (emphasis added); *see, e.g., Bowen v. American Hosp. Ass’n*, 476 U.S. 610, 618-19 (1986) (plurality opinion) (contrasting an “Interim Final Rule” on which HHS did not “solicit public comment” before promulgation with “Proposed Rules” on which “it invited comment”). Congress naturally incorporated that settled understanding into its authorization for the

Departments to issue interim final rules, *see Food Mktg. Inst. v. Argus Leader Media*, 139 S. Ct. 2356, 2362 (2019), and the Departments have relied on that understanding to issue interim final rules since shortly after Section 300gg-92 was enacted. *See, e.g.*, 62 Fed. Reg. 16,979 (Apr. 8, 1997); 62 Fed. Reg. 66,932 (Dec. 22, 1997); 63 Fed. Reg. 57,546 (Oct. 27, 1998).

Because the Secretaries were entitled to rely on their statutory authority to issue interim final rules as they “determine[d] appropriate,” the Secretaries were not required to adhere to the APA’s notice and comment requirement. The Plaintiffs’ claim of a procedural violation should be rejected.

B. The Defendants Had Good Cause to Issue the Interim Final Rule.

Even if the September interim final rule were subject to the APA’s notice and comment requirement, the Departments properly invoked the “good cause” exception to this requirement. This exception permits an agency to dispense with notice and comment where “the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.” 5 U.S.C. § 553(b)(B).

Although the good cause exception to the notice and comment requirement is narrow, it does permit agencies to depart from the default APA rulemaking procedures where the circumstances so warrant. This “good cause inquiry is inevitably fact- or context-dependent.” *Mid-Tex Elec. Co-op., Inc. v. FERC*, 822 F.2d 1123, 1132 (D.C. Cir. 1987). “[D]eviation from APA requirements has been permitted where congressional deadlines are very tight and where the statute is particularly complicated.” *Methodist Hosp. of Sacramento*, 38 F.3d at 1237; *see also United States v. Cain*, 583 F.3d 408, 422 (6th Cir. 2009) (“A deadline imposed by Congress before which an agency must regulate may support a finding of good cause, which makes sense because Congress can implicitly set aside the APA when it specifically requires rapid action.”). Although the Fifth Circuit has stated that a statutory deadline does not by itself constitute good cause, it has held that such a deadline “is a factor to be considered.” *U.S. Steel Corp. v. U.S. E.P.A.*, 595 F.2d 207 (5th Cir. 1979).

The Departments properly invoked the good cause exception by including in the Federal Register their finding that notice and comment would be impracticable and contrary to the public

interest. 86 Fed. Reg. at 56,043. In reaching this conclusion, the Departments noted that the major provisions of the No Surprises Act would go into effect on January 1, 2022, barely twelve months after these provisions were enacted, and that regulated entities would need months of lead time to prepare for the new legal regime. *Id.* at 56,043-56,044. First, the Departments found that health plans and health insurance issuers would have to account for the provisions of the interim final rule “in establishing premium or contribution rates and in making other changes to benefit designs,” and would “need time to secure approval for required changes in advance of plan or policy years.” *Id.* at 56,044; *see also, e.g.*, Letter from Katy Johnson, Senior Counsel, Health Policy, American Benefits Council, to Carol Weiser, Benefits Tax Counsel, U.S. Dep’t of Treasury, et al., at 28 (June 11, 2021) (noting that the forthcoming rules on the arbitration process “will, by necessity, be incredibly complicated” and will “require significant time and effort [for employers, health plans, and insurers] to implement”). Without sufficient lead time, insurers would be forced to guess at the possible content of a rule governing out-of-network payments. There is a close correlation between the amounts that insurers anticipate that they will need to pay providers for out-of-network services and the amounts that insurers set as premiums, and any lingering uncertainty over the particulars of the new legal regime would increase premiums further. *See, e.g.*, Duffy et al., 26 AM. J. MANAGED CARE at 403. The Departments thus properly found that prompt rulemaking was required to avoid increasing health care premiums, a result that would defeat the Act’s purpose of reducing health care costs.

Second, the Departments found that providers would need lead time to respond to the September rule’s new standards “regarding how they must initiate open negotiation and the Federal IDR process, as well as what information they must provide to certified IDR entities when engaging in the Federal IDR process.” 86 Fed. Reg. at 56,044. For many out-of-network medical services furnished on or after January 1, 2022, the Act prohibits certain health care providers from balance billing patients, and it directs those providers to the new statutory process for dispute resolution. But to present claims for payment to group health plans and health insurers after that date, providers needed advance notice of the types of information and the nature of the information that they would need to develop contemporaneously to support those claims. Given that an arbitrator will be

empowered to rule against a provider for its failure to provide contemporaneous information supporting the provider's payment claim, *see* 42 U.S.C. § 300gg-111(c)(5)(B)(i)(II), it was vitally important for the Departments to set the arbitration rules well in advance of the Act's effective date. *See, e.g.*, TMA Comment at 21 (noting that "there will be a very short turnaround [after the publication of the arbitration rule] for physicians and other providers to implement changes to their policies and procedures" and requesting "more time for compliance efforts").

On this score, the Departments recognized that they did not have the option of deferring the date on which the arbitration process would go into effect. The Act's prohibitions on balance billing went into effect on January 1. For providers who are now statutorily prohibited from balance billing patients, the absence of a functional arbitration process would mean that those providers could not recover full payment for out-of-network services either from patients or from insurers, resulting in "the possibility that [these providers] will be undercompensated for their services," 86 Fed. Reg. at 56,044, potentially threatening their viability and patients' access to medical care, *id.*

Third, the Departments found that prompt rulemaking was required to allow time for arbitrators to "acquire the necessary expertise and evidence of qualification to apply for certification in order to be prepared to conduct payment determinations for plan years beginning on or after January 1, 2022." *Id.* Upon issuing the interim final rule, the Departments gave arbitrators one month to review the rule's certification procedures and to submit requests for certification, leaving the Departments only two months to review applications and to complete the process of approving or rejecting those applications, in order for an approved list of arbitrators to be in place by the beginning of 2022. *See* Centers for Medicare & Medicaid Services, *Apply to become a certified Independent Dispute Resolution Entity*, cms.gov/nosurprises/help-resolve-payment-disputes/apply. Any further delay for the issuance of a proposed rule and then a final rule would not have left the Departments with sufficient time to perform their statutory duties to ensure that certified arbitrators meet the Act's standards for expertise and integrity. *See* 42 U.S.C. § 300gg-111(c)(4)(A).

These circumstances establish good cause for the Departments' determination that an interim rule was needed in advance of a final rule to be issued after notice and comment. It generally takes

federal agencies more than a year to complete the process of preparing a proposed rule; submitting a proposed rule to the Office of Management and Budget (“OMB”) for that agency’s review; publishing a proposed rule; allowing for a comment period; reviewing the comments that are submitted; preparing a final rule; submitting the final rule again to OMB; and publishing the final rule. *See* Anne Joseph O’Connell, *Agency Rulemaking and Political Transitions*, 105 N.W. L. Rev. 471, 513-19 (2011) (on average, even routine rulemakings take 1.3 years to complete, and significant rulemakings on average take four months longer). The Departments did not have the option to wait that long to issue their rules, given the need for advance planning shared by insurers, providers, and arbitrators alike.

Congress recognized this need for prompt action by directing the Departments to “establish by regulation” the arbitration process no later than December 27, 2021. 42 U.S.C. § 300gg-111(c)(2)(A). *See Petry v. Block*, 737 F.2d 1193, 1200-01 (D.C. Cir. 1984) (upholding interim final rule given the statute’s complexity and the short time frame to issue implementing regulations). Given “the regulated industry’s need for guidance” in advance of the Act’s effective date, and the Departments’ effort to provide that guidance under a specific Congressional authorization for interim final rulemaking, they had good cause to take the steps needed to create an arbitration system that would be able to function effectively from the outset. *See Coalition for Parity, Inc. v. Sebelius*, 709 F. Supp. 2d 10, 20 (D.D.C. 2010) (upholding interim rule issued under Section 300gg-92 to implement new statutory requirements); *see also Am. Transfer & Storage Co. v. ICC*, 719 F.2d 1283, 1293 (5th Cir. 1983).

Nor, contrary to the Plaintiffs’ claim, could the Departments have acted sooner. The No Surprises Act was enacted on December 27, 2020, and it directed the Departments first to set the methodology for determining the qualifying payment amount by July 1, 2021. 42 U.S.C. § 300gg-111(a)(2)(B). The Departments complied with Congress’s instructions in this regard by releasing the first interim final rule on the statutory deadline. *Requirements Related to Surprise Billing: Part I*, 86 Fed. Reg. 36,872 (July 13, 2021). (The Plaintiffs properly avoid suggesting that notice and comment was required for this rule.) The Departments needed to set this methodology first before they could move on to incorporate the qualifying payment amount into the rulemaking for the arbitration process that is set forth in the second interim final rule. *See* 86 Fed. Reg. at 56,044 (“These regulations [under the

second interim final rule] are intended to work in concert with the protections against surprise billing already instituted in the July 2021 interim final rules.”). That the Departments completed this rulemaking process within three months of the completion of the first interim final rule demonstrates that they acted with appropriate dispatch, not that they engaged in any delay.

C. Any Error in Promulgating the Interim Final Rule Was Harmless.

Ultimately however, this Court need not determine if the Departments failed to provide notice and comment because any failure was harmless. *See City of Arlington v. FCC*, 668 F.3d 229, 243 (5th Cir. 2012), *aff’d*, 569 U.S. 290 (2013); *see also* 5 U.S.C. § 706 (in reviewing agency action, “due account shall be taken of the rule of prejudicial error”). “The harmless error rule requires the party asserting error to demonstrate prejudice from the error.” *City of Arlington*, 668 F.3d at 243 (internal quotation omitted). The Plaintiffs here, however, fail to even allege prejudice. Nowhere in their complaint or in their motion for summary judgment do the Plaintiffs assert that they suffered any harm from the Departments’ issuance of the September rule without first providing for notice and comment. And, to the best of the Departments’ knowledge, neither TMA nor Dr. Corley submitted a comment on the rulemaking record in response to the September rule. This forecloses any possible claim that they suffered prejudice from the Departments’ rulemaking procedures. *See Am. Bankers Ass’n v. NCUA*, 38 F. Supp. 2d 114, 140 (D.D.C. 1999) (finding harmless error where the plaintiff “did not explain what it would have said had it been given an opportunity to respond”).

Nonetheless, had the Plaintiffs made the allegation, they could not meet their burden to show prejudice. “In conducting the harmless error inquiry, [the court informs its] analysis with a number of potentially relevant factors, including (1) ‘an estimation of the likelihood that the result would have been different’; (2) ‘an awareness of what body (jury, lower court, administrative agency) has the authority to reach that result’; (3) ‘a consideration of the error’s likely effects on the perceived fairness, integrity, or public reputation of judicial proceedings’; and (4) ‘a hesitancy to generalize too broadly about particular kinds of errors when the specific factual circumstances in which the error arises may well make all the difference.’” *City of Arlington*, 668 F.3d at 244 (quoting *Shinseki v. Sanders*, 556 U.S. 396, 411-12 (2009)). Each of these factors points toward a finding that any error was harmless here.

First, there is no indication that the Departments' conclusions would have been materially different had they first engaged in notice and comment. The Plaintiffs do not contend that the Departments failed to consider any relevant factual or policy issues in resolving statutory ambiguities at Step Two of the *Chevron* inquiry; instead, they raise a purely legal argument that the rule is foreclosed by the language of the statute. The Departments were aware of the Plaintiffs' legal argument, and simply arrived at a different reading of the statutory language. *See* 86 Fed. Reg. at 55,995-55,997. Second, Congress expressly entrusted the Departments with the authority to establish the arbitration process under the No Surprises Act, *see* 42 U.S.C. § 300gg-111(c)(2), and it did so by amending existing statutes that themselves expressly give the Departments interim final rulemaking power, *see* 42 U.S.C. § 300gg-92. Third, there is no reason to believe that the "error" will have any effect on the "perceived fairness, integrity, or public reputation of judicial proceedings." *City of Arlington*, 668 F.3d at 244.

Finally, the "specific factual circumstances in which the [alleged] error arises" also point against finding any prejudice here. *Id.* The Plaintiffs challenge portions of the second interim final rule that the Departments have issued to implement the No Surprises Act. TMA, however, addressed the arbitration standards in a comment it submitted in response to the first interim final rule, which raised the same legal argument that it now relies on. *See* TMA Comment at 16-17. It thus has had the opportunity to be heard by the Departments, and the Departments simply disagree with its reading of the statute. Moreover, the second interim final rule invited comments from the public, *see* 86 Fed. Reg. at 55,980, and the Departments will consider these comments prior to the promulgation of final rules. *See Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2385 (2020).

IV. ANY RELIEF SHOULD BE APPROPRIATELY LIMITED.

In the event the Court disagrees with the Departments' arguments, any relief should be no broader than necessary to remedy the demonstrated harms of the specific, identified plaintiffs in this case. "The Court's constitutionally prescribed role is to vindicate the individual rights of the people appearing before it." *Gill v. Whitford*, 138 S. Ct. 1916, 1933 (2018). So "[a] plaintiff's remedy must be tailored to redress the plaintiff's particular injury," *id.* at 1934, and "injunctive relief should be no more

burdensome to the defendant than necessary to provide complete relief to the plaintiffs,” *Madsen v. Women’s Health Ctr., Inc.*, 512 U.S. 753, 765 (1994) (citation omitted). Moreover, any relief should be limited to the particular provisions that the Plaintiffs have challenged. *See K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 294 (1988) (severing provisions of a regulation found to be invalid).⁹

At most, the Court should remand the matter to the Departments without vacatur of the challenged provisions because there is “at least a serious possibility that the agency will be able to substantiate its decision given an opportunity to do so.” *Tex. Ass’n of Mfrs. v. Consumer Prod. Safety Comm’n*, 989 F.3d 368, 389-90 (5th Cir. 2021) (remanding without vacatur to permit an agency to cure a notice-and-comment violation). “‘Only in ‘rare circumstances’ is remand for agency reconsideration not the appropriate solution.’” *Id.* (quoting *O’Reilly v. U.S. Army Corps of Eng’rs*, 477 F.3d 225, 238-39 (5th Cir. 2007)).

The Departments have begun the preparation of a final rule in response to the comments that they invited from the public on the September rule, and they intend to address those comments in publishing that rule. In the meantime, vacatur would be highly disruptive, as it would leave arbitrators with no guidance as to how to proceed with their decision-making, just as arbitrations are set to begin operating under the Act this spring. Patients, business groups, benefit administrators, insurers, and the public at large have a stake in a rule that will prohibit balance billing and that will reduce upward pressure on health care costs. These interests counsel heavily against vacatur. *See Cent. & S. W. Sems., Inc. v. EPA*, 220 F.3d 683, 692 (5th Cir. 2000).

CONCLUSION

For the foregoing reasons, the Defendants’ motion for summary judgment should be granted, and the Plaintiffs’ motion for summary judgment should be denied.

⁹ The Plaintiffs ask the Court to invalidate 45 C.F.R. § 149.510(c)(4)(vi)(B), which requires the arbitrator to prepare a written decision explaining why it determined the out-of-network payment rates to be materially different from the qualifying payment amount. Proposed Order, ECF No. 25-3. They offer no argument, however, to challenge the validity of this provision. This requirement is a straight-forward exercise of the Departments’ authority to require arbitrators to produce such information as may be necessary for the Departments to fulfill their own reporting obligations under the Act. 42 U.S.C. § 300gg-111(c)(7)(C).

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify on this 10th day of January, 2022, a true and correct copy of this document was served electronically by the Court's CM/ECF system to all counsel of record.

/s/ Joel McElvain
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